UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL ACTIONS	Judge Patti B. Saris

DEFENDANT AMGEN INC.'S REPLY MEMORANDUM IN FURTHER SUPPORT OF ITS INDIVIDUAL MOTION TO DISMISS THE AMENDED MASTER CONSOLIDATED COMPLAINT

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At the September 18, 2003, hearing, the Court flatly rejected "guilt by association" as an appropriate substitute for Rule 9(b), admonishing plaintiffs' counsel that plaintiffs cannot simply identify a defendant as a drug company, and from that, conclude that the company must have been involved in the unlawful manipulation of AWP. The Court made clear that plaintiffs must "plead the case against each drug and each company." The Amended Master Consolidated Complaint (the "AMCC") does neither. It does nothing to cure the defects of the prior complaint (which the Court dismissed in its entirety as to Amgen), and nothing plaintiffs argue in their opposition alters this conclusion. Accordingly, as to Amgen, the AMCC should be dismissed with prejudice.

Relying on hopelessly general allegations aimed at an entire industry, plaintiffs have yet to provide any specifics in support of their contention that Amgen engaged in wrongful conduct. As to Amgen, they do not, for example: point to the existence of any government investigation or audit involving AWP; identify a single allegedly fraudulent "spread" or any example of how Amgen supposedly marketed a spread; point to any internal or other documents evidencing or describing any improper pricing or marketing practice by Amgen; or provide even a single example of any allegedly unlawful sales and marketing practice. In the absence of at least some specific and supported factual averments that Amgen engaged in fraud, plaintiffs' conclusory allegations – which do not even rise to the level of allegations made on "information and belief" – cannot stand. *See Romani v. Shearson Lehman Hutton,* 929 F.2d 875, 878 (1st Cir. 1991).

Plaintiffs' continued reliance on generalized allegations that *defendants* were involved in a scheme to manipulate AWP is unavailing. Except for its identification of particular drugs and allegation that certain plans purchased certain drugs, the AMCC is

deficient because it contains no specifics about what Amgen did, how it did it, when it did it or where it did it. *U.S. ex rel. Franklin v. Parke-Davis,* 147 F.Supp.2d 39, 46 (D. Mass. 2001). Plaintiffs merely recycle the general description of the "AWP scheme" from their prior complaint, which the Court has already found lacking. As the Court previously has held, plaintiffs must allege fraud with particularity as to *each* defendant. *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F.Supp.2d 172, 194 (D. Mass. 2003).

Although plaintiffs contend "the government has documented inflated AWPs for both epoetin alfa and filgrastim," s*ee* Opposition at 22, this assertion is not anchored to any allegation in the AMCC, and plaintiffs cite to no study, audit or investigation to support it. Amgen, virtually alone among defendants named in these cases, simply has not been named in any government investigation or inquiry relating to AWP.[1]

By the same token, plaintiffs' assertion that Amgen has "acknowledged" its supposed involvement in "over-reimbursement as a corporate-wide mechanism to gain market share," by reference to Amgen's recent legal challenge to various rulemaking procedures is, in a word, frivolous. In that case, filed after the plaintiffs commenced this AWP litigation, Amgen challenged under the Administrative Process Act ("APA") a decision by the U.S. Department of Health and Human Services ("DHHS") to reduce Medicare reimbursement for Amgen's new product, Aranesp®. The district court held that Amgen did not have standing to challenge the agency's action under the APA because it was not an intended beneficiary under Medicare. The case (which is outside of the pleadings in any event) simply cannot be

[1] Plaintiffs' lament that Amgen has provided no discovery misses the point. It is precisely *because* Amgen has not been the subject of a government investigation or audit or Congressional inquiry that Amgen has not produced documents. Plaintiffs' new fallback position that they need discovery from Amgen at least tacitly acknowledges the deficiency of their current complaint, the futility of allowing further amendment and underscores why Amgen should be dismissed with prejudice. In any event, the fact that Amgen has not produced documents certainly does not entitle plaintiffs to conduct discovery in the hope of finding support for their claims. *See, e.g., Romani,* 929 F.2d at 878; *Parke-Davis,* 147 F.Supp.2d at 46 (Rule 9(b) intended, in part, to prevent fishing expeditions).

read to stand for the proposition that Amgen engaged in, much less acknowledged its involvement in, the unlawful manipulation of AWP, as plaintiffs suggest.

Lastly, plaintiffs' reliance on a "1993 OIG Report" is disingenuous. That report was prepared in connection with DHHS' consideration more than a decade ago of possible changes to the *statutorily fixed reimbursement rate* for Epogen®.[2] The report had nothing whatsoever to do with AWP-based reimbursement. The study, moreover, does not suggest that Amgen's rebates were in any way improper. In fact, although the Office of the Inspector General ("OIG") recommended that the Health Care Financing Administration ("HCFA") consider reducing the statutory reimbursement rate to reflect end-of-year rebates, HCFA rejected that recommendation, even noting "that the elimination of rebates . . . would not result in a change in the manufacturer's price, nor would it serve any program end." OIG A-01-92-00506 (incorrectly cited by plaintiffs as OIG A-01-02-00506).

These facts notwithstanding, plaintiffs take the argument one step further in an effort to conjure up evil intent on Amgen's part by pointing to its alleged unwillingness prior to 1993 to provide sensitive pricing and rebate information to DHHS, from which plaintiffs infer that "disclosure of the rebates would have revealed AWP manipulation." As the report makes clear, however, the agency was able to obtain the information from other sources. More to the point, the study dealt with the statutorily-fixed (that is, non-AWP) reimbursement rate for Epogen® and thus could not conceivably support the inference that plaintiffs hope to draw. In fact, in light of the government's obvious awareness of the rebates and their effect on pricing, it is frankly more reasonable to infer the *absence* of any improper manipulation, given the lack of any investigative interest or follow up.

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[2] Plaintiffs acknowledge that virtually all Medicare reimbursement for Epogen® is not based on AWP, but is set by statute. Opposition at 25. There is thus no dispute that, to the extent plaintiffs seek recovery based upon Medicare Part B reimbursements for Epogen® that are not based on AWP, these claims must be dismissed.

CONCLUSION

For the reasons set forth herein, and in Amgen's initial memorandum in support of its motion, Amgen respectfully submits that the Amended Master Consolidated Complaint, as to it, should be dismissed with prejudice.

Respectfully submitted,

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